REMARKS

The portion of the claims relevant to the restriction of Groups I, II, and III, recites a Markush group:

> said recombinant virus comprising a nucleic acid selected from the group consisting of:
> (a) nucleic acids encoding a mutated form of p53 which antagonizes wild-type p53-mediated neuronal cell degeneration *in vitro*;
> (b) the site for binding of p53 to DNA; and
> (c) nucleic acids encoding an antisense RNA which inhibits expression of p53.

See, Appendix, claim 16 and claim 22. By way of restriction, the Office has required Applicants to split this Markush-style claim into three different inventions, one for each of the elements recited in the Markush group.

The only explanation given for the restriction of Groups I, II, and III in the Office Action mailed October 2, 2001, reads as follows:

> Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are related to different methods, restriction is deemed to be proper between the methods of I-IV since they constitute patentably distinct inventions comprising different methodologies, different recombinant viruses encoding or comprising different active agents operating by different mechanisms by processes involving different technical considerations (e.g. mutant proteins, binding sites antisense RNAs) or reagents (e.g. glutamate), method steps (measurement of excitotoxicity), and technical considerations and/or endpoints as a whole requiring separate non-coextensive searches.

Office Action mailed October 2, 2001, pages 3-4.

Applicants contend that this "explanation" is merely a conclusory statement lacking any supporting rationale. The Office alleges that the inventions of groups I, II, and III, are "different" in a number of ways, without providing any details that actually

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establish those alleged differences. Moreover, as discussed below, the statement ignores established restriction practice.

The criteria for restriction of Markush-type claims is set forth in M.P.E.P. § 803.02, which states:

> If the members of the Markush group are sufficiently few in number, or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not require restriction.

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. M.P.E.P. § 803.

The Office has not suggested that there are an unreasonable number of members in the claimed Markush group. There are, in fact, only three members. Thus, this point is not disputed. Instead, the Office contends that the inventions each possess differing technical features so that a search for one member of the Markush group is not coextensive with the others, *i.e.*, causes an undue burden. Applicants disagree. There is no basis for concluding that the search of Groups I, II, and III is unduly burdensome.

A search poses a serious burden if the inventions have a separate classification, a separate status in the art, or a different field of search. M.P.E.P. § 808.02. This same section of the M.P.E.P. defines these terms as follows:

> (A) **Separate classification thereof**: This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.
>
> (B) **A separate status in the art when they are classifiable together**: Even though they are classified together, each subject can be shown to have formed a separate subject for inventive effort

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> when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.
>
> (C) **A different field of search**: Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

The Office has offered no basis for concluding that searching the subject matter of Groups I, II, and III would constitute a burden. The Office acknowledges that the inventions of Groups I, II, and III all are classified in the same class and subclass (class 424, subclass 93.2). Office Action mailed October 2, 2001, page 2. This suggests that each subject has not "attained recognition in the art as a separate subject for inventive effort, and also a separate field of search." M.P.E.P. § 808.02.

Even though the inventions are classified together, however, they may still have attained a separate status in the art if an explanation indicates a recognition of separate inventive effort by inventors. This is not the case here. The present inventors describe the unity of the elements of the claimed Markush group as "compounds which at least partially inhibit the activity of the p53 protein." Specification, page 3, lines 10-15. Such compounds include those that act on the synthesis of p53 at the transcriptional, translational, or post-translational levels, or the binding of p53 to DNA. *Id.* Thus, the groups in the Markush claim are recognized by the inventors as all belonging to the same class of p53 inhibiting compounds. This suggests that each subject has not attained a separate status in the art. M.P.E.P. § 808.02.

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Finally, the Office may show a serious burden if the inventions each require a separate field of search, *i.e.*, places where art is searched for one subject contain no pertinent art to the other subjects. The Office contends that this is the case, arguing that "the search for the invention of group I would not be coextensive with that of groups II and III." Office Action mailed April 11, 2002, page 3.

Applicants contend that the Office's statement runs counter to the information disclosed in the scientific literature. In preparing this Petition, Applicants briefly searched recent scientific literature on the publicly available PUBMED database. The search revealed multiple documents that describe various p53 binding sites and mutant forms of p53 in the same document. The search also revealed multiple documents that describe both mutant forms of p53 and antisense nucleic acids that disrupt p53 expression. The scientific literature is full of such publications, where more than one type of p53 inhibiting molecule is described in the same publication. Copies of representative abstracts from this brief review of the recent literature are attached. Applicants contend that these abstracts clearly establish that a search for one subject will reveal information that is pertinent to the other subjects. Thus, groups I, II, and III, do not require different fields of search. This also supports Applicants contention that the groups have not achieved a separate status in the art. Rather, they are commonly described together in the same scientific experiments.

In summary, groups I, II, and III possess the same art classification, have not attained a separate status in the art, and do not require different fields of search. Consequently, there is no undue burden posed by searching the three groups together.

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Thus, Applicants contend that there is no reason to divide the groups and request that the Office's improper restriction requirement be withdrawn.

Additionally, Applicants respectfully submit that they have a statutory right under 35 U.S.C. § 112, second paragraph, to claim the subject matter they regard as their invention as they choose. Issuing a restriction requirement within a claim that forces Applicants to carve up that claim and pursue the nonelected subject matter in a separate application violates this right under section 112. Indeed, the C.C.P.A. has characterized such action as tantamount to a refusal to examine. *See In re Weber*, 198 U.S.P.Q. 328 (C.C.P.A. 1978); *In re Haas*, 198 U.S.P.Q. 334 (C.C.P.A. 1978).

In *Weber*, the court warned against the consequences of requiring an applicant to divide up the subject matter presented in a single claim, stating:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Weber at 331.

The Office has provided no substantive reason to violate Applicants' statutory right under 35 U.S.C. § 112, second paragraph, to claim the subject matter they regard as their invention as they choose. Thus, in order to avoid unnecessary delay and expense to Applicants, and duplicative examination by the Patent Office, the restriction among Groups I, II, and III should be withdrawn.

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solicited. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: August 9, 2002

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